IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

CHARLENE EIKE, SHIRLEY FISHER, JORDAN PITLER and ALAN RAYMOND,

Plaintiffs,

vs.

ALLERGAN, INC., *et al.*,

Defendants.

Case No. 12-cv-1141-SMY-DGW

MEMORANDUM AND ORDER

This matter comes before the Court on Defendants' Motion to Exclude the Testimony of Brian Kriegler, Ph.D. (Doc. 185) and Motion to Exclude Portions of the Expert Testimony of Dr. Alan Robin, M.D. (Doc. 187). The Court held a hearing on the motions on April 14, 2015. For the following reasons, the motions are **DENIED**.

Plaintiffs' First Amended Complaint alleges Defendants' practices of selling topical prescription ophthalmic pharmaceuticals are unfair, unethical and unconscionable and violate the Illinois Consumer Fraud & Deceptive Business Practices Act, 815 ILCS 505/1, *et seq*. ("ICFA") and the Missouri Merchandising Practices Act, Mo. Rev. State. § 407.010, *et seq*. ("MMPA"). Specifically, Plaintiffs allege the following nine counts: Count I – ICFA Violations of Allergan; Count II – MMPA Violations of Allergan; Count III – ICFA Violations of Alcon; Count IV – MMPA Violations of Alcon; Count V – ICFA Violations of Bausch; Count VI – MMPA Violations of Bausch; Count VII – MMPA Violations of Pfizer; Count VIII – ICFA Violations of Merck; and Count IX – ICFA Violations of Prasco.

Legal Standard

Admissibility of expert testimony is governed by Federal Rule of Evidence 702. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. In *Daubert*, the Supreme Court held that Rule 702 requires district judges to be gatekeepers for proposed scientific evidence. *Daubert*, 509 U.S. at 589; *see also General Elec. v. Joiner*, 522 U.S. 136, 142 (1997). For scientific evidence to be admissible, a district court must find it both relevant and reliable; it must be scientific knowledge grounded "in the methods and procedures of science" and consist of more than "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589-90.

In 2000, Rule 702 was amended in response to *Daubert*. In its current form, it provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

When analyzing scientific expert testimony, the preliminary question is "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93. Considerations pertinent to this inquiry include whether a theory or technique is capable of being or has been tested, whether it has been subjected to peer review and publication, its known or potential rate of error when applied, and whether it has gained general acceptance. *Id.* at 593-94; *accord Conn*, 297 F.3d at 555. Rule 702's advisory committee's note suggests courts also consider:

> (5) whether "maintenance standards and controls" exist; (6) whether the testimony relates to "matters growing naturally and directly out of research they have conducted independent of the litigation," or developed "expressly for purposes of testifying"; (7) "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion"; (8) "[w]hether the expert has adequately accounted for obvious alternative explanations"; (9) "[w]hether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting"; and (10) "[w]hether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give."

Fed. R. Evid. 702 advisory committee's note (2000 amends.); *accord Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 534-35 (7th Cir. 2005), *vacated in part on other grounds*, 448 F.3d 936 (7th Cir. 2006), *cert. denied*, 127 S. Ct. 1151 (2007).

To determine if an expert is qualified to testify on a particular matter, a court should "consider a proposed expert's full range of practical experience as well as academic or technical training." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). However, generalized knowledge within an area is not necessarily sufficient to qualify an expert:

> [A]n expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise. Generalized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge.

Martinez v. Sakurai Graphic Sys. Corp., No. 04 C 1274, 2007 WL 2570362, at * 2 (N.D. Ill. Aug. 30, 2007) (citing *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994)).

Brian Kriegler Ph.D (Doc. 185)

Dr. Kriegler, a statistician, developed a model to estimate Plaintiffs' damages in this case. His model first calculates the total amount of sales of eye drops during the proposed class period, and then uses Defendants' eye drop studies that estimated the difference between the average size of eye drops and a specified bench mark of 16 microliters ("µL"). The percentage difference

between the two represents the amount of medicine wasted, as a percentage of all medicine purchased by class. The amount of money lost by each proposed class member then would be computed as the total cost of the eye drops paid by class members multiplied by the amount of medicine wasted. Defendants contend Dr. Kriegler's methodology is fundamentally flawed and unreliable.

First, Defendants argue Dr. Kriegler's methodology is unreliable because it assumes that drop volumes calculated by Defendants pursuant to strict laboratory controls represent actual drop volumes obtained by glaucoma patients in the real world. They argue this assumption exceeds Dr. Kriegler's expertise; is not the product of any discernible statistical methodology or principles; and is nothing more than unqualified, improper, and inaccurate narration of Defendants' discovery. Plaintiff counters that Kriegler's use of Defendant's data was proper because Defendants themselves stated they performed the tests to "mimic actual patient use of the product," "simulate patient use of the product," "deliver drops in the same way as someone using the product," "simulate practical use and evaluate the total yield, number of drops and drop size," and "confirm consistency of the drug product delivery" (Doc. 176-6). Plaintiff further argues that Defendants' challenges to Dr. Kriegler's methodology are best left to cross-examination.

The Seventh Circuit has held that the reliability inquiry under *Daubert* "is primarily a question of the validity of the methodology employed by an expert, not the quality of the data used in applying the methodology or the conclusion produced." *Manpower, Inc. v. Ins. Co. of Pennsylvania*, 732 F.3d 796, 806 (7th Cir. 2013). Questions related to the quality of the underlying data and the expert's conclusions are not a proper consideration in assessing the reliability of the expert's methodology. *Id.* In *Manpower,* the district court excluded plaintiff's

forensic accounting expert's testimony who opined as to plaintiff's business interruption and extra expense losses. *Id*. at 801. The district court concluded that the expert's methodology was accurate, but excluded the testimony because he did not "use reliable methods when selecting the numbers used in his calculations – specifically projected revenues and projected total expenses." *Id*. The district court explained that "[o]nly a more thorough analysis of the reasons for the growth would have supported [the expert]'s choice of a projected growth rate." *Id*. The Seventh Circuit held the district court abused its discretion in excluding the expert and specifically found the district court's reliability inquiry should have ceased after determining the expert's methodology was reliable. *Id*. at 807. The court explained that "the selection of data inputs to employ in a model is a question separate from the reliability of the methodology reflected in the model itself." *Id*.

Here, similar to the opponents of the expert testimony in *Manpower*, Defendants are challenging the reliability of the data inputs Dr. Kriegler used in his model. However, his use of data supplied in discovery was not improper or unreliable as experts commonly use data supplied in litigation. While the propriety of Dr. Kriegler's selection of data inputs may be relevant to the weight to be accorded his testimony, it is not a proper admissibility inquiry for this Court to make under *Daubert*.

Next, Defendants assert that Dr. Kriegler's methodology is over-inclusive because his model reimburses patients for medicine they accidentally waste when administering eyedrops, which is unrelated to excess drop volume. Plaintiffs counter that this argument misrepresents their damages claim which is based on the allegation that the average drop size of each product should have been 16 µL instead of the larger existing size. The Court agrees that Defendants' argument mischaracterizes Plaintiffs' claims. It is irrelevant that patients missed their eyes or

engaged in other wasteful activities when administering eye drops. Plaintiffs' claim is that the individual drops were too large and that they were therefore forced to pay for non-therapeutic portions of the large drop size. Had Defendants' droppers administered the proposed 16 µL, Plaintiffs still would have purchased a smaller volume for even the wasted drops. As such, Dr. Kriegler's failure to consider wasted drops does not render his model unreliable.

Finally, Defendants argue that Dr. Kriegler's methodology would provide Plaintiffs with windfall damages because he does not use data reflecting the amounts patients pay to purchase drugs, ignores that the requested re-design will come at a substantial cost to Defendants and assumes each microliter in a bottle correlates proportionately to the retail price of drugs. Again, to the extent Defendants take issue with Dr. Kriegler's data selection, that argument goes to the weight of the evidence – not the admissibility under *Daubert*.

For the foregoing reasons, the Court **DENIES** Defendants' Motion to Exclude the Testimony of Brian Kriegler, Ph.D.

Dr. Alan Robin, M.D. (Doc. 187)

Dr. Robin is Plaintiffs' ophthalmology expert. He opines "…that any drop size larger than an average of 5-15 µL is larger than the capacity of the eye and provides more medication than necessary" (Doc. 176-2, p. 7). In support of his opinion, he states "the literature indicates that larger drops are no more effective than drops of 15 µL or even smaller." *Id.* He concludes, "To prevent undue waste of medication, eye drops should probably be no larger than 15 µL…but "to be conservative my recommendation would be that drops be no larger than 16 µL." *Id.* He further states his "…findings do not demonstrate that there are individual issues regarding whether patients would benefit from smaller drop sizes." *Id.* He further states that a dropper capable of emitting these smaller drops is commercially available/viable. Defendants contend

Dr. Robin's testimony as to the recommended size of eyedrops is unreliable and that his testimony regarding the feasibility of a smaller dropper and the reason Defendants did not use a smaller dropper should be excluded because Dr. Robin is not qualified to give such an expert opinion, the testimony is hearsay and Dr. Robin has not been disclosed as a fact witness.

Defendants first argue that Dr. Robin's eyedrop size testimony is unreliable because (1) he relies on articles and studies presented in a summary and conclusory fashion while failing to explain the methodology of the studies, why the methodologies are allegedly reliable or how the studies support his ultimate conclusion; (2) his conclusions lack the support of reliable and accepted scientific methodology and are thus inadmissible; and (3) the studies themselves lack reliability because they are based on inadequate sample sizes, involved an irrelevant population and/or relate to non-glaucoma medications or medications not at issue in this case.

"An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Mid-State Fertilizer Co. v. Exch. Nat'l Bank of Chi.*, 877 F.2d 133, 1339 (7th Cir. 1989). For instance, in *United States v. Noel*, the expert's testimony was unreliable because her "'expert testimony' that the photos met the definition of child pornography was a bare conclusion that provided nothing but the bottom line," but "[h]ad the expert provided some basis for this explanation, perhaps her testimony would have been of some use for the jury." 581 F.3d 490 (7th Cir. 2009).

Here, in light of the *Daubert* factors, Dr. Robin's opinion that eye drops should probably be no larger than 15 µL is sufficiently reliable. Unlike the expert in *Noel*, Dr. Robin provides multiple bases for his opinion. His report cites to several studies which support his conclusion. The Allergan Microdrop Study "confirms that small eye drops, even as small as 5 µL, provide effective treatments" (Doc. 176-2, p. 23), and the NODS Study found that an eyedrop "delivered

in doses eight times *smaller* than those in commercially available eye drops were equally effective . . ." (Doc. 176-2, p. 23). Notably, the Vocci Study, of which Dr. Robin was the senior author and principal investigator, compared the efficacy of 16 µL and 30 µL drops and concluded that the 16 µL drops had the same therapeutic benefit as the 30 µL drops. Dr. Robin's theory has been tested and has been subject to peer review and publication. Dr. Robin indicates his agreement with the following passage from an article in a peer-reviewed publication from the University of Chicago Department of Ophthalmology and Pharmacy Practice: "Studies have shown that the bioavailability and efficacy of drops as small as 15 µL are equivalent to those of larger drops" (Doc. 176-2, p. 6). *See also* Doc. 196, p. 31 (Plaintiff lists published articles supporting Dr. Robin's opinion). Finally, the multiple cites to articles agreeing with Dr. Robin's opinion suggest that it has been generally accepted in the relevant community. As such, the Court is not persuaded that Dr. Robin is merely giving a "bottom line opinion".

Defendants next contend that because Dr. Robin's area of expertise is ophthalmology, he is not qualified to opine about the commercial feasibility of a dropper that can deliver drops smaller than 16 µL and that his opinions about the feasibility of the dropper and why such a dropper has not been introduced are based on unreliable hearsay. Plaintiffs assert that with respect to this particular testimony, they are offering Dr. Robin as a fact witness, not an expert witness. Plaintiffs further contend that Dr. Robin's testimony in this regard is not hearsay, but rather is admissible pursuant to Fed. R. Evid. 801(d) as an opposing party's statement. Defendants indicate that Plaintiffs did not disclose Dr. Robin as a fact witness in their Rule 26 initial disclosures or written discovery.

Federal Rule of Civil Procedure 37 (c)(1) provides that "exclusion of non-disclosed evidence is automatic and mandatory…unless non-disclosure was justified or harmless." District

courts have broad discretion in evaluating whether a Rule 26 violation is harmless. *Alexander v. Mount Sinai Hosp. Med. Ctr.*, 484 F.3d 889, 901-02 (7th Cir. 2003). The Court looks to several factors when determining whether noncompliance with Rule 26 is justified or harmless, including whether a party was prejudiced or surprised by the nondisclosure, the ability to cure the prejudice, the likelihood of disruption at trial, and bad faith or willfulness. *Tribble v. Evanglides*, 670 F.3d 753, 760 (7th Cir. 2012).

Defendants were aware of the subject matter of Dr. Robin's testimony and that he would potentially testify as an expert witness. They cannot claim surprise and the Court fails to see the harm or prejudice Defendants will suffer simply because certain testimony is being offered through Dr. Robin as a fact witness versus an expert witness. Further, to the extent Dr. Robin's testimony as to the feasibility of the dropper and why such a dropper has not been introduced is based on an opposing party's statement, is does not constitute inadmissible hearsay.

For the foregoing reasons, the Court **DENIES** Defendants' Motion to Exclude Portions of the Expert Testimony of Dr. Alan Robin, M.D.

DATED: September 14, 2015

s/ Staci M. Yandle
STACI M. YANDLE
DISTRICT JUDGE